

Macropore TS: Anti-Adhesion Film

- **RATIONAL:**

Scarring adjacent to the exiting nerve roots has been implicated in failed back syndrome.

• STRATEGY:

510(k) submitted: January 19, 2001*

*(this will not have the same indications as Gliatech - PMA)

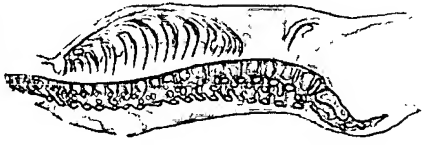
MARKET SIZE:	US	EU	Total
	\$25+	\$5	\$30+

Macropore TS:

Indications for Use (submitted)

- 1) Surgical repair of fractured orbital floors
- 2) Surgical repair of nasal septum and perforated ear drum membrane
- 3) Used as a protective sheathing to facilitate osteogenesis
- 4) For surgical repair of urethral anatomy and repair of urethral strictures
- 5) To prevent synostosis in completed corrective surgery for cranial fusions and forearm fractures
- 6) Lessen soft-tissue fibrosis or bony growth
- 7) As a temporary covering for prenatal rupture omphalocele during

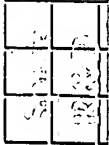
Not suitable for repairing permanent implants are required.



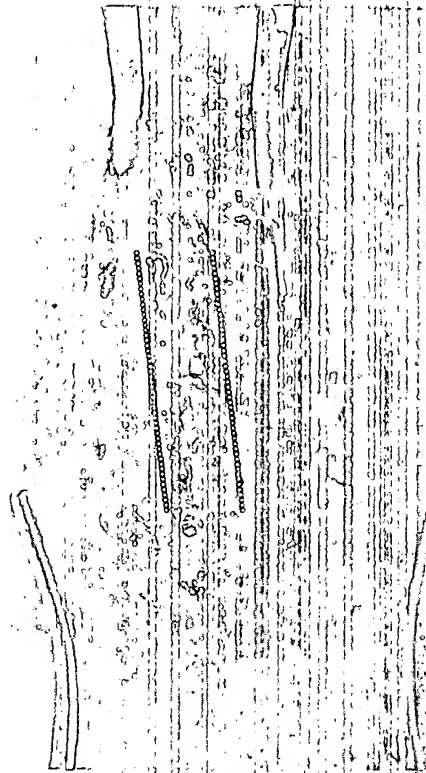
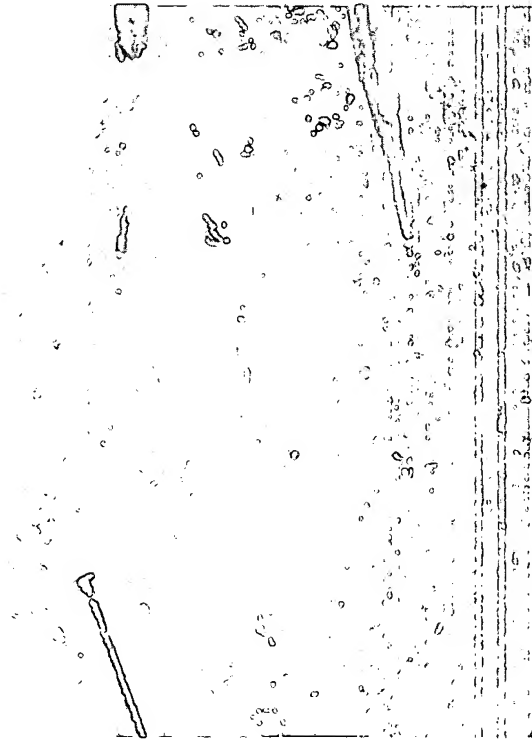
Spine Research

- [illegible]

penicillin are supplemented when penicillin is required.



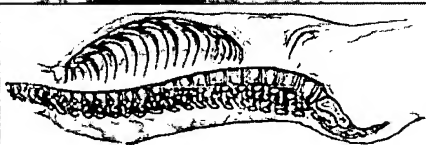
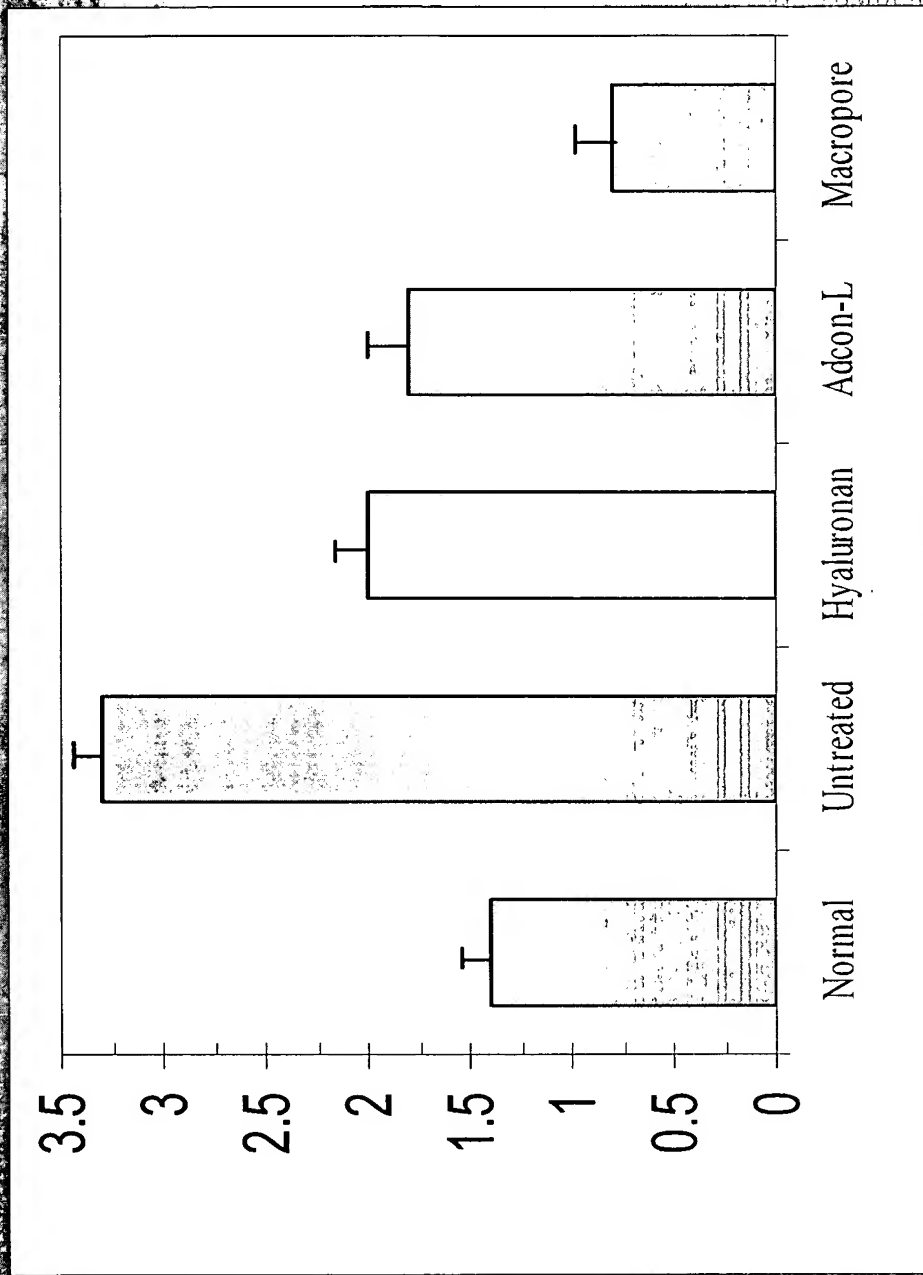
L5-L6 Laminectomy-Dura



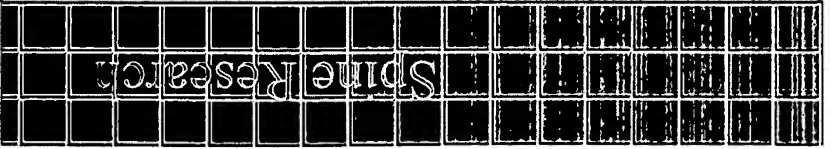
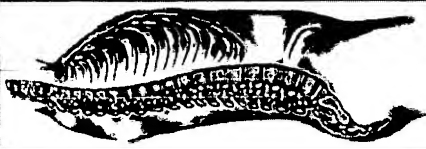
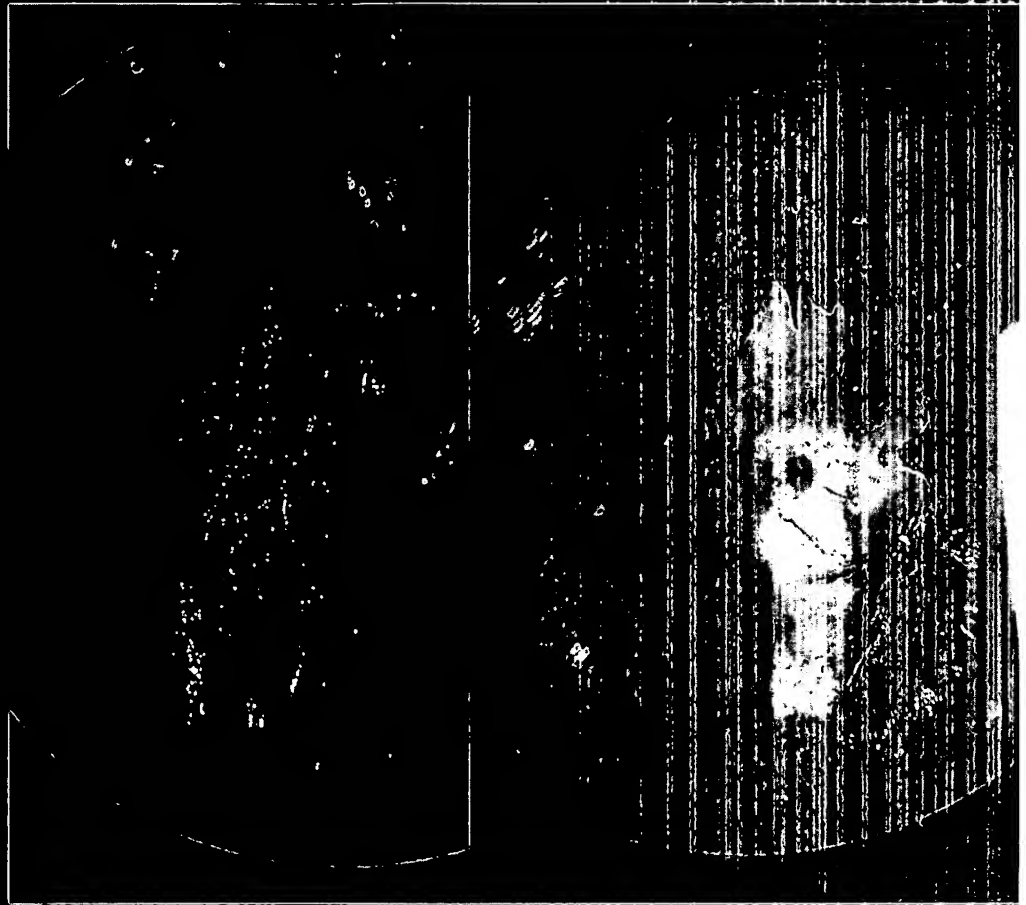
MacroPore TS:

Anti-Adhesion Study

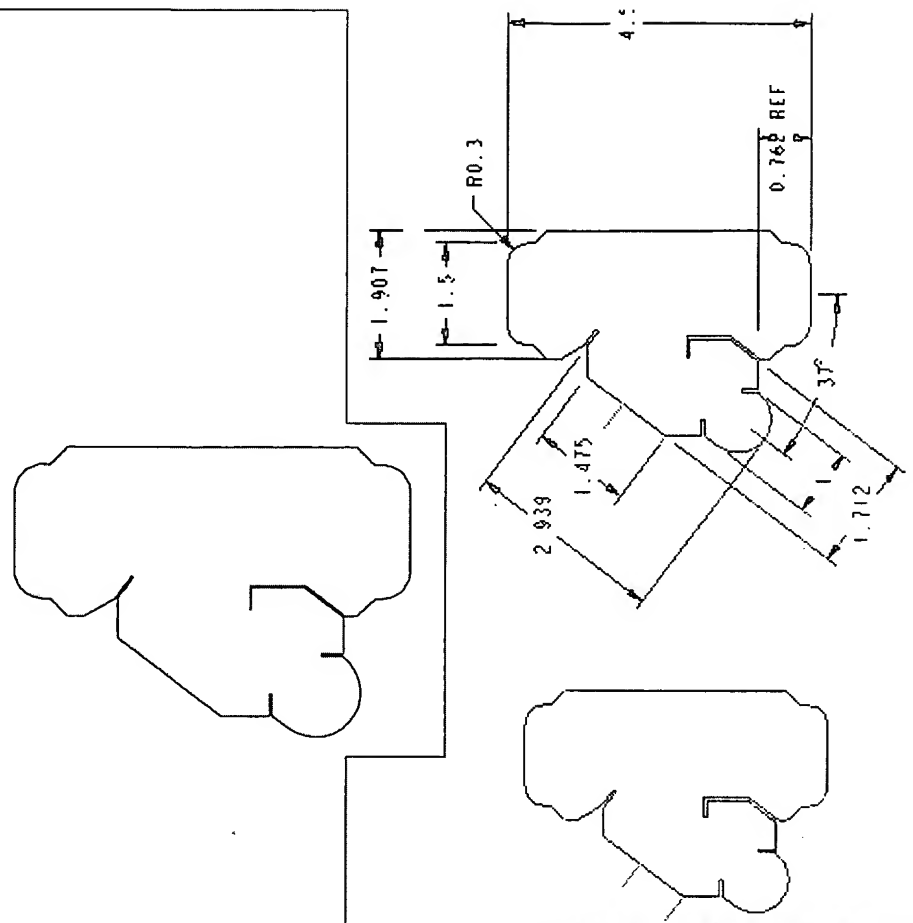
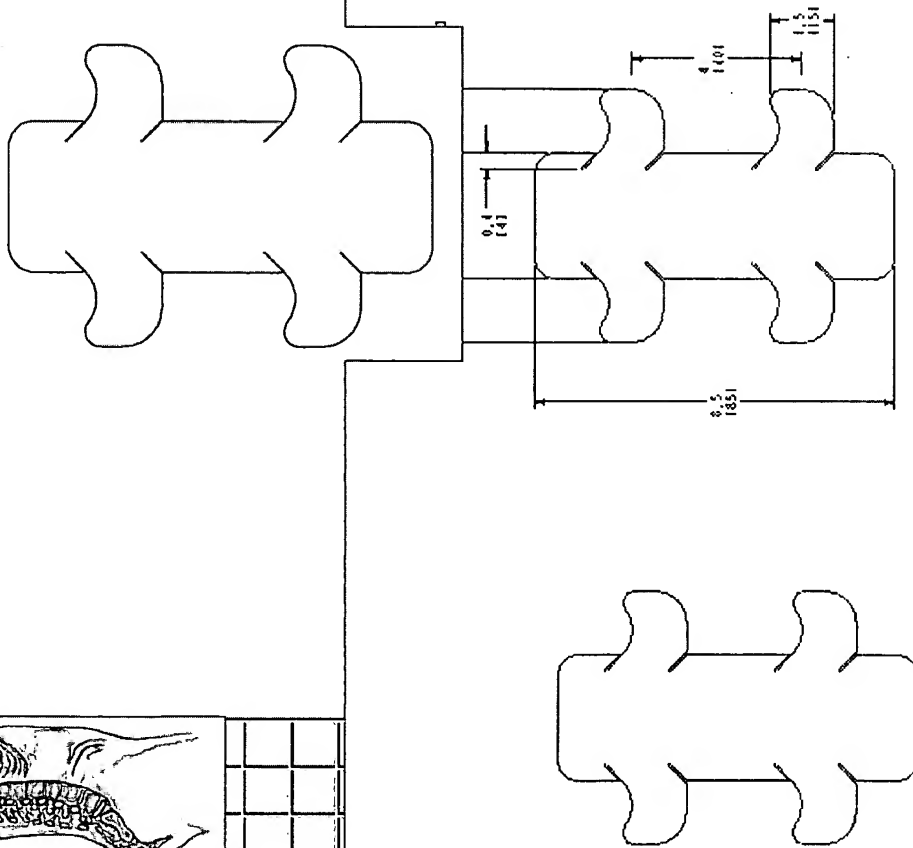
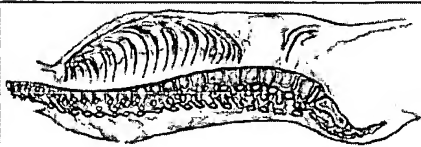
Total Collagen Content of Epidural Space



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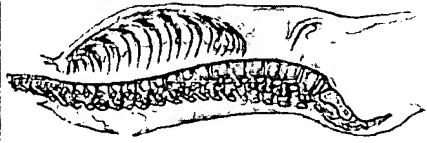


TYPE - PART NAME - 803-0001-REV-01 SIZE - A

TYPE - PART NAME - 803-0003-REV-1 SIZE - A

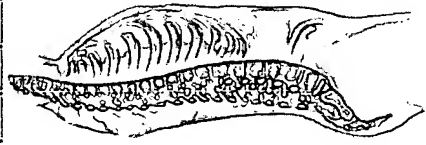
Literature Review

- The degradation of PLA implants does not seem to create any sinus formations or significant pH variance according to clinical data and animal testing
- Properly sterilized PLA does not appear to cause unusual infection or foreign body reaction
- PLA is more accepted by the body than PGA, another common bioresorbable material



Conclusions

- Early pre-clinical results (rat model) demonstrate quantitative reduction in collagen content – associated with scar.
- PLA is a biocompatible & safe material.
- Surgeon Interest & Excitement in this product is STRONG!



Spine Research